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FOR

INTERVERTEBRAL DISC PROSTHESIS AND METHODS OF IMPLANTATION

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"INTERVERTEBRAL DISC PROSTHESIS AND METHODS OF
IMPLANTATION"

Cross Reference to Related Application

This application claims the benefit of Provisional Application Number

5 60/262,974, filed January 17, 2001.

Field of the Invention

The present invention generally relates to a prosthesis to replace an injured
intervertebral disc. The present invention further relates to methods for

10 implanting the intervertebral disc prosthesis into the spinal column.

Background of the Invention

The spinal column, which is the central support to the vertebrate skeleton
and a protective enclosure for the spinal cord, is a linear series of bones, or

15 vertebrae. Intervertebral discs separate and reduce friction between adjacent
vertebrae and absorb compression forces applied to the spinal column. Spinal
nerves that extend from each side of the spinal cord exit the column at
intervertebral foramina.

A typical vertebra comprises an anterior body, and a posterior arch that surrounds the spinal cord lying within the vertebral foramen formed by the arch. The muscles that flex the spine are attached to three processes extending from the posterior arch. On the upper surface of each vertebra in a standing human are two
5 superior articulated processes that oppose two inferior articulated processes extending from the lower surface of an adjacent vertebra. Facets on the opposing processes determine the range and direction of movement between adjacent vertebrae, and hence the flexibility of the spinal column.

The intervertebral discs include the fibrillar cartilage of the anulus
10 fibrosus, a fibrous ring, the center of which is filled with an elastic fibrogelatinous pulp that acts as a shock absorber. The outer third of the anulus fibrosus is innervated. The entire spinal column is united and strengthened by encapsulating ligaments.

Back pain is one of the most significant problems facing the workforce in
15 the United States today. It is a leading cause of sickness-related absenteeism and is the main cause of disability for people between ages 19 and 45. Published reports suggest that the economic cost is significant, treatment alone exceeding \$80 billion annually. Although acute back pain is common and typically treated with analgesics, chronic pain may demand surgery for effective treatment.

20 Back pain can occur from pinching or irritation of spinal nerves, compression of the spine, vertebral shifting relative to the spinal cord axis, and bone spur formation. The most common cause of disabling back pain, however, stems from trauma to an intervertebral disc, resulting from mechanical shock,

stress, tumors or degenerative disease, which may impair functioning of the disc and limit spinal mobility. In many cases, the disc is permanently damaged and the preferred treatment becomes partial or total excision.

Another cause of back injury is herniation of the intervertebral disc, wherein the gelatinous fluid of the nucleus pulposus enters the vertebral canal and pressures the spinal cord. Again, surgery is often the only method available for permanent relief from pain or the neurological damage ensuing from the pressure of fluid on the spinal cord, and requires replacement of the damaged disc.

Traumatic injury to an intervertebral disc that is not removed will frequently promote scar tissue formation. Scar tissue is weaker than original healthy tissue so that the disc will progressively degenerate, lose water content, stiffen and become less effective as a shock absorber. Eventually, the disc may deform, herniate, or collapse, limiting flexibility of the spinal column at that position. The only option is for the intervertebral disc to be partially or totally removed.

When the disc is partially or completely removed, it is necessary to replace the excised material to prevent direct contact between hard bony surfaces of adjacent vertebrae. One vertebral spacer that may be inserted between adjacent vertebrae, according to U.S. Patent No. 5,989,291 to *Ralph et al.*, includes two opposing plates separated by a belleville washer or a modified belleville washer. The washer provides a restorative force to mimic the natural function of the disc by providing a shock absorber and mobility between adjacent vertebrae. An alternative approach is a "cage" that maintains the space usually occupied by the

disc to prevent the vertebrae from collapsing and impinging the nerve roots. However, mechanical devices intended to replicate intervertebral disc function have had only limited success.

- Spinal fusion may be used to restrict the motion between two vertebrae that comes from segmental instability. Fusing the vertebrae together, however, reduces the mechanical back pain by preventing the now immobile vertebrae from impinging on the spinal nerve. The disadvantage of such spacers is that stability is created at the expense of the flexibility of the spine.

- Surgical procedures for replacing intervertebral disc material, rather than fusing of the vertebrae, have included both anterior approaches and posterior approaches to the spinal column. The posterior approach (from the back of the patient) encounters the spinous process, superior articular process, and the inferior articular process that must be removed to allow insertion of the disc replacement material into the intervertebral space. The anterior approach to the spinal column is complicated by the internal organs that must be bypassed or circumvented to access the vertebrae.

- Many intervertebral spacers require preparation of the surfaces of the adjacent vertebrae to accommodate the spacer, causing significant tissue and bone trauma. For example, chiseling or drilling of the vertebral surface may be required to prepare a receiving slot. They may also require screwing the spacer into the intervertebral space, making installation difficult and increasing trauma to the vertebral tissue. Many spacers include complex geometries and are costly to manufacture. Examples of such geometrically complex spacers are described in

U.S. Patent No. 5,609,636 to *Kohrs et al.*, U.S. Patent No. 5,780,919 to *Zdeblick et al.*, U.S. Patent No. 5,865,848 to *Baker* and U.S. Patent No. 5,776,196 to *Matsuzaki et al.*

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Summary of the Invention

The present invention provides an intervertebral disc prosthesis that can be inserted relatively easily by the surgeon into the intervertebral space while causing minimal trauma to the opposing surfaces of the vertebrae as well as to the bony processes. The present invention further provides a simple biocompatible spacer that may be implanted into a patient while causing reduced injury to the surrounding tissues and organs.

The present invention provides biocompatible intervertebral disc prostheses that are resilient to compressive forces, that may be adapted to an intervertebral space and when implanted in the spinal column of a patient will maintain the separation between adjacent vertebrae, provide shock absorbent protection and allow flexibility of the spinal column. The present invention further provides methods for the implantation of the intervertebral disc prosthesis of the present invention into the spinal column of a human or animal patient.

One aspect of the present invention, therefore, is an intervertebral disc prosthesis comprising a body adapted to fit an intervertebral space between adjacent vertebrae, wherein the body comprises a resilient biocompatible material. The body of the intervertebral disc prosthesis can be selected from a monolayer sheet, a laminate comprising a plurality of layers, a block, a disc, an annulus and a

ribbon. The plurality of layers of the laminate may be fastened to each other by at least one fastener selected from a suture, a staple, a clip, an adhesive or by cell invasion into and between the laminated layers. The intervertebral disc prosthesis is comprised of a resilient biocompatible material selected from a dissected
5 human or animal tissue, an inorganic polymer, an organic polymer, or any combination thereof.

In one aspect of the present invention the intervertebral disc prosthesis is derived from a dissected human or animal pericardium that is fixed by the protein cross-linking agent glutaraldehyde, detoxified and treated with an anti-
10 calcification process. The intervertebral disc prosthesis may further be treated with a blood anti-coagulant.

Another aspect of the present invention is a method of maintaining an intervertebral space between adjacent vertebrae, comprising the steps of excising at least a portion of an intervertebral disc, thereby creating a receiving slot, and
15 inserting into the receiving slot at least one intervertebral disc prosthesis comprising a resilient biocompatible material according to the present invention. The further surgical step of removing a minimal portion of the bony process of a vertebrae to create access to the damaged intervertebral disc may be included in the method of the present invention

20 Various other objects, features, and advantages of the invention will become more apparent upon review of the detailed description set forth below when taken in conjunction with the accompanying drawing figures, which are briefly described as follows.

Brief Description of the Figures

Fig. 1 is an exploded perspective view of a portion of the human spinal column, showing the body of an intervertebral disc prosthesis according to the
5 present invention inserted between adjacent vertebrae.

Fig. 2 is a side-elevation of the intervertebral disc prosthesis, shown in
Fig. 1, illustrating an intervertebral disc prosthesis inserted between two adjacent
vertebrae, wherein an anterior face of the prosthesis is thicker than the posterior
10 face.

Fig. 3A shows a perspective view illustrating an intervertebral disc
prosthesis in the form of a folded sheet of detoxified resilient biocompatible
material secured by a suture.
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Fig. 3B shows a perspective view of a folded sheet intervertebral disc
prosthesis between two adjacent vertebrae as viewed from the front (anterior) of
the patient.

20 Fig. 3C shows a perspective side-view of a folded sheet intervertebral disc
prosthesis between two adjacent vertebrae.

Fig. 4A illustrates the implantation of an intervertebral disc prosthesis, in the form of a ribbon of resilient biocompatible material, into an incision in an intervertebral disc.

Fig. 4B illustrates a longitudinal section through two adjacent vertebrae and the intervertebral disc and showing, *in situ*, an intervertebral disc prosthesis, in the form of a ribbon of resilient biocompatible material confined within an intervertebral disc.

Detailed Description

A full and enabling disclosure of the present invention, including the best mode known to the inventor of carrying out the invention, is set forth more particularly in the remainder of the specification, including reference to the accompanying drawings, wherein like reference numerals designate corresponding parts throughout several figures. This description is made for the purpose of illustrating the general principles of the invention and should not be taken in the limiting sense.

Examples of intervertebral disc prostheses 10 in accordance with the present invention are shown in Figs. 1-4B. An intervertebral disc prosthesis 10 of the present invention can support adjacent vertebrae 20 after partial or total surgical excision of an intervertebral disc 21. It is contemplated that the intervertebral disc prostheses 10 of the present invention may be used to replace an intervertebral disc 21 that has degenerated due to traumatic injury, vertebral

displacement, disease such as, for example, autoimmune disease or rheumatoid arthritis or any other abnormal condition of the spinal column that may injure or shift the intervertebral disc. The intervertebral disc prostheses 10 of the present invention provide support to the vertebrae 20. The resilience of the material
5 selected for use in an intervertebral disc prosthesis 10 provides shock absorbance protection to the spinal cord 22.

The intervertebral disc prosthesis 10 of the present invention includes a body adapted to fit within the intervertebral space 23 between adjacent vertebrae 20. It is intended that the material of the intervertebral disc prosthesis 10 of
10 present invention is any biocompatible material having a degree of resilience that can provide a level of shock absorbance when the prosthesis is implanted in the spinal column of a patient. It will be understood that a biocompatible material is non-toxic to the tissues of a recipient human or animal patient, and will elicit a non-injurious immune reaction, or is non-immunogenic. A biocompatible
15 material may support the invasion of cells from the recipient patient's own tissues into the intervertebral disc prosthesis 10. Such biocompatible materials may be selected from, but are not limited to, a tissue dissected from a human or animal, a synthetic organic or synthetic inorganic polymer, or any combination thereof. An example of a particularly useful biocompatible tissue is a human or animal
20 pericardium. An example of a biocompatible tissue particularly useful in the present invention is the treated bovine pericardium DURA SHIELD™ (Shelhigh, Inc., Milburn, New Jersey). Examples of synthetic materials that are useful in the present invention are GORLEX™ and PROLEAN™.

The dissected tissue that comprises the intervertebral disc prosthesis 10 of the present invention may be treated to reduce immunogenicity, which is the ability of an implanted tissue to elicit an immune response in a recipient human or animal. Furthermore, the dissected tissue may be treated with a protein cross-linking agent such as, but not limited to, glutaraldehyde before implantation into the patient.

Any biocompatible tissue may be further treated with an anti-calcification process so that the tissue does not harden, stiffen, or otherwise become brittle after implantation into the intervertebral space or treated with an anti-coagulant such as, but not limited to, heparin.

Any treated biocompatible material for use in an intervertebral disc prosthesis 10 of the present invention may be rendered non-toxic to the recipient patient by a detoxification process, especially, but not only, after treatment of a dissected tissue from a human or animal with a fixing agent. It is also contemplated that the intervertebral disc prostheses 10 of the present invention can be sterilized, before implantation into a patient, by any suitable method known to those skilled in the art and which will not degrade any of the desired mechanical or biological properties of the prosthesis. An example of a method of sterilization and storage of an intervertebral disc prosthesis 10 of the present invention is soaking in benzyl alcohol, which rapidly evaporates before insertion into the patient.

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Examples of tissue detoxification and anti-calcification treatment processes, such as the NO-REACT[®] process (Shelhigh, Inc., Milburn, New Jersey), and the design and construction of a detoxified biocompatible tissue such as DURA SHIELD[™] (Shelhigh, Inc., Milburn, New Jersey) that are suitable materials for the intervertebral disc prosthesis of the present invention are described in *Abolhoda et al.*, Ann. Thoracic Surg. 62, 1724-1730 (1996); *Abolhoda et al.*, Ann. Thoracic Surg. 62, 169-174 (1996); *Infantes & Angell*. Adv. Anticalcific and Antidegenerative Treatment of Heart Valve Bioprostheses, pp 221-231, ed: *Gabbayid S. & Wheatley D.J.*, pub: Silent Partners, Inc., Austin (1997), which are incorporated herein by reference in their entirety

In the embodiments of the intervertebral disc prosthesis 10 of the present invention, the body of the intervertebral disc prosthesis 10 may be selected from any geometrical form including, but not limited to, a rectangle, square, circle, and an annulus and which is capable of maintaining the intervertebral space 23 and which will allow mobility and flexibility of the spinal column.

In other embodiments of the present invention, the intervertebral disc prosthesis 10 may further comprise a spacer comprised of a non-resilient biocompatible material selected from the group consisting of a metal such as titanium, a plastic, an inorganic polymer, an organic polymer or a combination thereof. It is contemplated that the spacer may be configured to be compressible, and therefore capable of absorbing compressibility forces applied to the spinal column of the patient.

In one embodiment of the intervertebral disc prosthesis **10** of the present invention, the intervertebral disc prosthesis **10** has multiple surfaces, including an anterior face **11** and a posterior face **12**, wherein the anterior face **11** is directed towards the inner body cavity of the patient, and the posterior face **12** is directed towards the dorsal surface of the patient. The intervertebral disc prosthesis **10** may be configured such that the thickness of the anterior face **11** is greater than the thickness of the posterior face **12**, as is illustrated in Fig. 2 or the thickness of the posterior face **12** is greater than the thickness of the anterior face **11**. The difference in the thickness of the opposing anterior **11** and posterior **12** faces of the intervertebral disc prosthesis **10** of the present invention may be selected to preserve the natural curvature of the spinal column.

In another embodiment of an intervertebral disc prosthesis **10** of the present invention, the intervertebral disc prosthesis **10** is a folded sheet **14**, as shown in Fig. 3A. The sheet **14** can be further adapted, folded or otherwise manipulated to fit within and maintain an intervertebral space **23** between adjacent vertebrae **20**, as shown in Figs. 3B and 3C. The sheet **14** can be secured within the intervertebral space **23** by a first fastener **15** including, but not limited to, a staple, suture, an adhesive, or any other fastening material that can further prevent unfolding of the sheet **14**, and which will not significantly impede movement of the vertebrae. Optionally, unfolding of the sheet **14** can be prevented by a first fastener **15** and the prosthesis **10** secured within the intervertebral space **23** by a second fastener **19**.

In still another embodiment of an intervertebral disc prosthesis **10** of the present invention, the intervertebral disc prosthesis **10** can be a laminate comprising a plurality of layers of the biocompatible material. The plurality of the laminated layers can be secured by a first fastener **15** such as, but not limited to, a staple, a suture, an adhesive, or by fusing the layers together to form the laminate body or cultivating cells within and between the layers, thereby holding the layers in the laminate.

In yet another embodiment of intervertebral disc prosthesis **10** of the present invention, as shown in Fig. 4A and Fig. 4B, the intervertebral disc prosthesis **10** is a ribbon **16** of resilient biocompatible material removed from a sheet **14** of the biocompatible material. The sheet **14** of resilient biocompatible material may further comprise at least one predetermined line **17** selected from an indentation, a plurality of indentations or a plurality of partial perforations that can facilitate the removal of the ribbon **16** from the sheet **14**. The ribbon **16** of the implantable resilient biocompatible material will allow the surgeon to select the amount of the material to be implanted into an intervertebral space **23**, thereby accommodating variations in the size of the intervertebral space **23** in different patients or between different pairs of vertebrae **20**. It will further allow the surgeon to insert the material into the intervertebral space **23** with a minimal removal of tissue for access to the implantation site.

In the embodiment illustrated in Fig. 4B, the ribbon **16** may be inserted into the interior of an intervertebral disc **21** that has been hollowed by surgical removal of intervertebral disc tissue or as a result of disc herniation. The ribbon

16 may be inserted through a narrow incision 18 into the intervertebral disc 21 and the ribbon 16 confined therein by the residual intervertebral disc 21.

It is contemplated by the present invention that the biocompatible material of the intervertebral disc prosthesis 10 can be invaded by cells. The proliferating
5 cells may be derived from the patient, or are cells implanted into the intervertebral disc prosthesis before, during, or after implantation into the patient. The cells that can invade an implanted intervertebral disc prosthesis of the present invention include, for example, vascular or neural cells, or chondrocytes. Such cell growth and penetration into an implanted intervertebral disc prosthesis can strengthen the
10 prosthesis and resist slippage of the implant from the intervertebral space.

The present invention further provides a method of using the intervertebral disc prosthesis 10 to maintain the intervertebral space 23. The method of the present invention comprises a surgical procedure for anteriorly or posteriorly installing at least one intervertebral disc prosthesis 10 into an intervertebral space
15 23 between adjacent vertebrae 20. The intervertebral disc prosthesis 10 can be inserted into the intervertebral space 23 while removing only a portion of the bony process of the adjacent vertebrae 20 so as to minimize trauma to the patient from the surgical procedure. It will be understood by those skilled in the art that the amount of bone removal required for placement of the intervertebral disc
20 prosthesis 10 within an intervertebral space 23 will depend upon the conformation of the vertebrae 20 and spinal column of the individual patient. The intervertebral disc prosthesis 10 can be slid between the adjacent vertebrae 20, thereby minimizing bone removal and reducing the risk of injury to the neural tissue.

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The method of the present invention for inserting the intervertebral disc prosthesis 10, as contemplated herein, comprises excising a portion of the intervertebral disc 21 separating adjacent vertebrae 20 thereby creating a receiving slot. The method may further include removing material from at least one vertebra 20. At least one intervertebral disc prosthesis 10 is inserted into the intervertebral space 23 to support and maintain the separation of adjacent vertebrae 20.

The method of the present invention may further comprise the step of implanting an intervertebral spacer between adjacent vertebrae 20. The method of the present invention may also further comprise the step of delivering a substance that, in the intervertebral space 23, will have a consistency ranging from a semi-solid state to a solid state. Examples of suitable substances useful in the present invention include, but are not limited to, a silicone-based polymer, methyl acrylate, a collagen-based gel, or a plastic.

With respect to the above description, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly, and use, are deemed readily apparent and obvious to one skilled in the art, and all equivalent relationships to those illustrated in the drawing and described in the specification are intended to be encompassed by the present invention. Further, the various components of the embodiments of the invention may be interchanged to produce further embodiments and these further embodiments are intended to be encompassed by the present invention.

Although the invention has been described in detail for the purpose of illustration, it is understood that such detail is solely for that purpose, and variations can be made therein by those skilled in the art without departing from the spirit and scope of the invention which is defined by the following claims.

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